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PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Gibbins, Bruce L. et al.

Serial No.: **09/752,939**

Filed: **December 29, 2000**

For: METHODS AND COMPOSITIONS FOR IMPROVED DELIVERY DEVICES

Art Unit: **1615**

Examiner: **Ghali, Isis A. D.**

DECLARATION under 37 CFR § 1.132

1. I, Bruce L. Gibbins, Ph.D. am the founder of AcryMed, Inc., and currently serve as Chief Technology Officer and Chairman of the Board for AcryMed, Inc. of Beaverton, Oregon. I am an inventor of the above-referenced patent application. I received my Ph.D. in Bacteriology and Public Health from Washington State University and was a professor of microbiology at Otago Medical School in Dunedin, NZ. I founded AcryMed, Inc. in 1993.

2. Under my direction and knowledge, the following experiments were performed at AcryMed, Inc. to compare the product made as taught by U.S. Patent Application Publication No. 2002/0042587 to Murdock (hereinafter "Murdock Article") to an embodiment of the invention of U.S. Patent Application Serial No. 09/752,939 to Gibbins, et al. (hereinafter "AcryMed Matrix").

3. **MATERIALS USED:**

AcryMed Matrix:

23.9 g acrylamide	0.250 ml TEMED
0.29 g N'N'N'-methylene bis acrylamide	0.36 g ammonium persulfate
2.66 g uar gum	411 g de-ionized water
24.2 g glycerol	0.83 g sodium carbonate

463 g total mass

Murdock Article

10 g Polyvinyl Alcohol (98-99% hydrolyzed, Mw = 85K-124K, Batch # 03628MC)
90 g Deionized Water

IKA Werke Ultra-turrax T25 model lab mixer

Oxygen Delivery Study:

300 ml BOD (biological oxygen demand) bottles (Wheaton)

Diamond General Chemical Sensor (Clark Probe for dissolved oxygen measurement)

4. SYNTHESIS OF MURDOCK ARTICLES

1) Heat water with stir bar to 90°C.
2) Slowly add polyvinyl alcohol (PVA)
3) Continue stirring until all PVA has dissolved into solution.

Two batches of Murdock Articles were made by following methods as taught in Example 1 & Example 2 of US 2002/0042587.

Batch 1 (similar to Example 1 of Murdock): Murdock 1

1) 100 ml of PVA solution was stirred using IKA Werke Lab Mixer at 3000 rpm for 20 minutes inside a Captair GloveTM tent with 1ATM/100% oxygen gas environment.
2) ~6 gms of the resulting solution was poured into 60 mm diameter petri dishes. Samples were sealed in foil pouches containing 100% oxygen.
3) The petri dishes with foamed PVA were placed in a -20°C environment for 24 hr. The petri dish with the foamed article was removed from the freezer and gradually warmed to room temperature.

Batch 2 (similar to Example 2 of Murdock): Murdock 2

1) 100 ml of PVA solution was stirred using IKA Werke Lab Mixer at 3000 rpm for 20 minutes inside a Captair GloveTM tent with 1ATM/100% oxygen gas environment.
2) ~6 gms of the resulting solution were poured into 60 mm diameter Petri dishes. Samples were sealed in foil pouches containing 100% oxygen.

3) The petri dishes with foamed PVA underwent three cycles of exposure to -20°C for 2 hours and warming to ambient room temperature for 30 minutes.

5. PREPARATION OF THE ACRYMED MATRIX

A. Matrix preparation

1). Prepared a solution of 2.66 g guar gum in 10 ml IPA.
2). Added acrylamide, bis-acrylamide, glycerol, and sodium carbonate with 300 g of de-ionized water in beaker with stir bar.
3). While constant stirring, slowly added guar gum:IPA mixture 1 ml add a time.
4). Combined 50 g de-ionized water and 0.250 ml TEMED. Added to beaker and mixed for 1-2 minutes.
5). Combined 50 g de-ionized water and 0.36 g ammonium persulfate. Add to beaker and mix 1-2 min.
6). Poured gel mixture into gel casting unit and allow to polymerize into gel slabs.

Gel Drying

7). Gel slabs were removed from gel casting unit, placed into high airflow dryer for 5 hours @ 45° C to form gel sheets, which were then cut to appropriately size pieces.

Hydrogen Peroxide Treatment

8). Gel sheets were submerged in 20% hydrogen peroxide v/v in de-ionized water for 90 seconds.
9). Gel sheets were then dried in a no air flow oven for 2h @ 55°C.

6. EXPERIMENTAL DATA

EXPERIMENT 1 RATE OF OXYGEN DELIVERY INTO A FLUID MEDIUM (SALINE)

Oxygen released into a fluid medium (saline) was measured using a Diamond General Chemical Microsensor- Clark Style Electrode. 4 cm^2 (2 cm X 2 cm) pieces of each sample (Murdock Articles and AcryMed Matrix) were placed into the dissolved oxygen measuring apparatus. The apparatus contained 11 ml of saline. To ensure that the saline had the same level of oxygen at time 0, air was bubbled through the saline. This is shown by the partial pressure of oxygen at time 0 of approximately 159 mmHg. (At sea level 1 atmosphere of pressure is 760 mmHg of mercury (British standard) and oxygen is ~21% of atmospheric air, so the partial pressure of oxygen is ~159mmHg). Dissolved oxygen measurements, as partial

pressure (mmHg), were recorded every 5 minutes over a 30 minute time course. The data is shown below in Table 1 which corresponds to the three figures.

Table 1 (mmHg)

Time	Murdock 1	Murdock 2	Acrymed
0	158	155	154
5	172	163	224
10	185	166	263
15	191	167	290
20	193	168	315
25	194	170	334
30	193	170	350

Figure 1

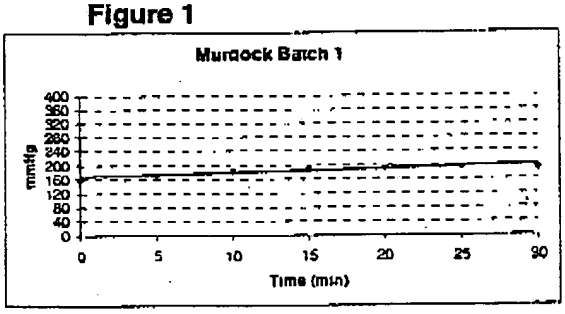


Figure 2

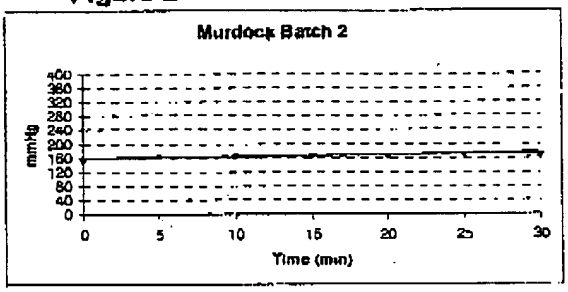
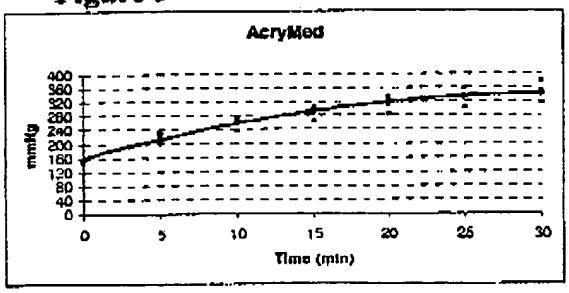


Figure 3



EXPERIMENT 2- Measurement of total deliverable Oxygen from samples

Samples from each of Murdock and Gibbins were each placed in a B.O.D. (biological oxygen demand) bottle, filled with 300 ml diH_2O and the lids were sealed. Dissolved oxygen recordings were made at 24 hours. Each sample was circular with a diameter of 60 mm.

Table 2

Sample	Weight (g)	Change in mmHG	ppm Oxygen delivered	O_2% of Material wt/wt
Murd-1-A	6.0	22.96	< 0.1	<0.0005%
Murd-1-B	5.76	16.07	< 0.1	<0.0005%
Murd-2-A	6.4	6.89	< 0.1	<0.0005%
Murd-2-B	5.4	2.30	< 0.1	<0.0005%
Acrymed A	0.37	265.58	2.8	0.23%
Acrymed B	0.22	222.72	2.7	0.37%

EXPERIMENT 3 Visual Appearance

A. After formation

Figure 4 A
Murdock

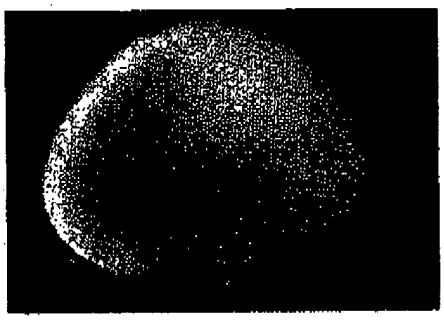
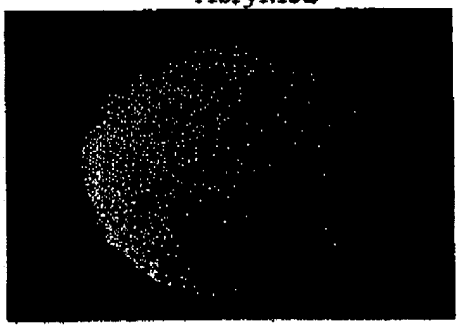


Figure 4 B
AcryMed



The Murdock article appears as a mostly continuous polymeric article with extremely small closed cells, spaced irregularly and of an inconsistent size. The Murdock article has a gelatinous wet feel.

The AcryMed matrix has closed cells of a regular and uniform size, spaced throughout polymeric matrix. The AcryMed dressing has a dry feel.

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B. Physical characteristics following 24 hr soak in water (wet).

Figure 5A
Murdock

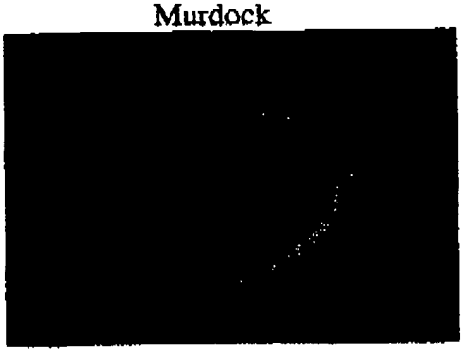
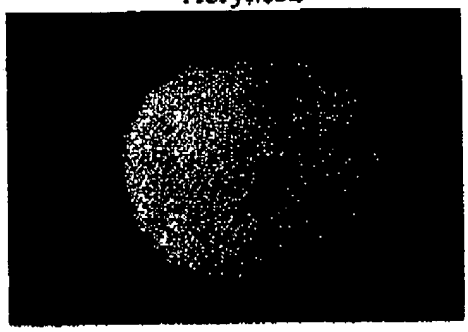


Figure 5B
AcryMed



The Murdock article has lost a significant amount of material weight with a few closed-cells still visible. The article has become almost transparent and is easily pulled apart.

The AcryMed matrix appears consistent in shape. The size of the individual closed-cells has decreased but the regular spacing remains. The AcryMed matrix remains intact and difficult to pull apart.

7. I acknowledge under the penalty of perjury pursuant to 18 U.S.C. § 1001, that willful false statements and the like are punishable by fine or imprisonment, or both, and may jeopardize the validity of the above identified patent application or any patent issuing from the above identified patent application.

_____
Bruce L. Gibbins, Ph.D.

Date:_____